

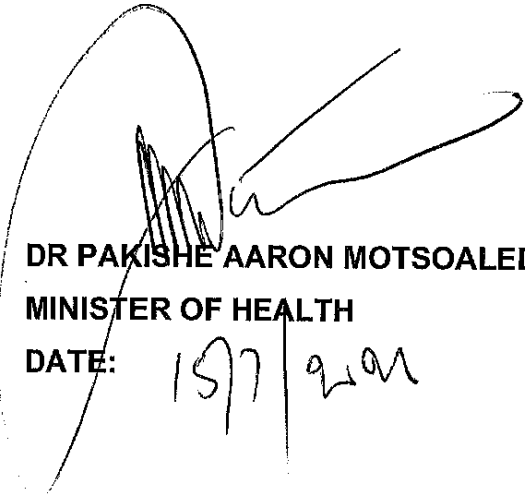
DEPARTMENT OF HEALTH

NO. 7780

7 August 2026

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)**GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED
SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965): AMENDMENT**

The Minister of Health has, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), and after consultation with the South African Health Products Regulatory Authority, made the regulations in the Schedule.



DR PAKISHE AARON MOTSOLEDI, MP
MINISTER OF HEALTH

DATE: 15/7/2021

SCHEDULE

Definitions

1. In these regulations —

"the Act" means the Medicines and Related Substances Act, 1965 (Act 101 of 1965); and

"the Regulations" means the General Regulations as published under Government Notice 859 in *Government Gazette* 41064 of 25 August 2017."

Amendment of regulation 1

2. Regulation 1 is hereby amended —

(a) by the deletion of the definition of **"counterfeit medicine"**;

(b) by the insertion after the definition of "Site Master File" of the following definition:

"substandard medicine" means a medicine that fails to meet either its quality standards or specifications or both."; and

(c) by the insertion after the definition of "expiry date" of the following definition:

"falsified medicine" means a medicine for which the identity, composition or source is deliberately or fraudulently misrepresented".

Amendment of regulation 6

3. Regulation 6 is hereby amended —

(a) by the substitution of sub-regulation (1) of the following sub-regulation-

"(1) No person shall import any medicine or scheduled substance, including medicines imported in terms of section 15C of the Act, into the Republic except through one of the following ports of entry, in a manner as determined by the Authority:

(a) Cape Town International Airport or Cape Town harbour;

(b) Chief Dawid Stuurman International Airport, Port Elizabeth harbour or Ngqura harbour;

(c) King Shaka International Airport or Durban harbour; or

- (d) O.R. Tambo International Airport.” and
- (b) by the insertion after sub-regulation (1) of the following sub-regulation:
- “(1A) Despite sub-regulation (1), a person may import any medicine or scheduled substance in a manner as determined by the Authority through-
- (a) Beit Bridge border post (Zimbabwe border);
 - (b) Vioolsdrift border post (Namibia border);
 - (c) border post (Botswana border);
 - (d) Maseru Bridge border post (Lesotho border);
 - (e) Lebombo border post (Mozambique border);
 - (f) Oshoek border post (Eswatini border), provided that the Authority is notified of and approves the intended importation.”
- (c) by the addition after sub-regulation (3) of the following sub-regulation:
- “(4) No person shall import or export any scheduled substances, medicines, or health products unless a permit has been issued to him or her by the CEO or Authority in the prescribed manner and subject to such conditions as may be determined by the CEO or Authority.”.

Amendment of Regulation 51

4. Regulation 51 is hereby amended by the substitution in sub-regulation (1) for paragraph (b) of the following:
- “(b) is suspected of being falsified.”

Short title

5. These Regulations are called General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act No.101 of 1965): Amendment, 2026